



Corrective Action / Preventive Action

Our CAPA training is designed to meet the requirements mandated by the FDA to effectively investigate and locate causes and correct them. Attendees learn proper identification of non-conformances (problems), how to assess and prioritize them based on risk, and how to implement a proper corrective and/or preventive action.

“After receiving training through PathWise, we certainly see a general improvement in our CAPA process, including Root Cause Analysis and Documentation.

There is also a reduction in the number of open CAPAs, resulting in less people being involved and less pressure for our organization.”

- **Hans Willems**
VP Operations
Boston Scientific

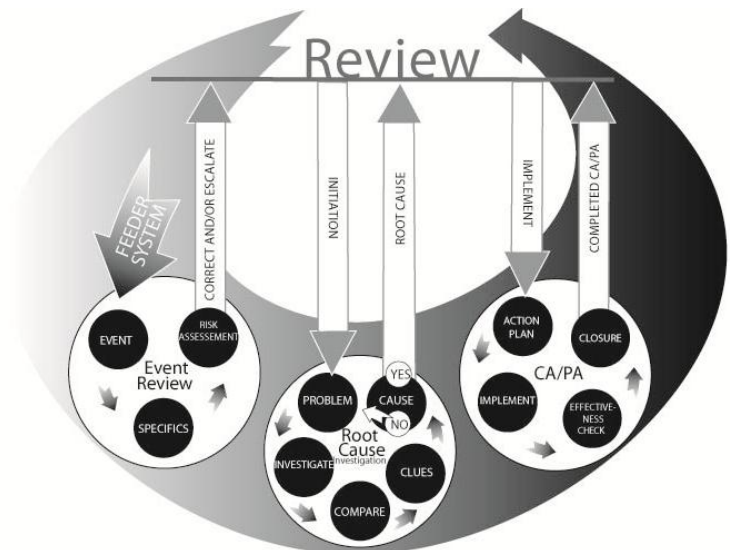
COURSE OVERVIEW

- Introduction
- Event Review
- Risk Assessment
- Investigator Toolkit
- Root Cause Analysis
- Implementation

LEARNING OBJECTIVES

Throughout the training, participants improve their ability to:

- Minimize repeat investigations.
- Reduce length and number of investigations.
- Identify true root causes.
- Lower overall costs associated with quality events.
- Pinpoint root causes using facts instead of guesswork or opinion.
- Avoid costly experiments and trial fixes by logically testing possible causes.
- Assess and prioritize each Event based on risk.
- Target potential problems before they happen and develop actions to prevent them.
- Check effectiveness of corrective actions in the CAPA system.
- Ensure proper documentation of the CAPA report.



AUDIENCE & DELIVERY

CAPA is appropriate for individuals who are regularly called upon to resolve problems, or whose input would aid in preventing problems. Examples include investigators, laboratory, QA/RA functions, managers, manufacturing supervisors, technicians, and engineers.

PathWise not only provides an outside perspective to these issues, we bring proven best-practices, tools, and processes. We've studied the best of the best in the life sciences field, and bring an intimate knowledge of the FDA regulations.

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PathWise